1C002453

AUG 31 2000

Section 1 D: SUMMARY OF SAFETY AND EFFECTIVENESS for the Access® Toxo IgM II assay

1. 0 General Information

Device Generic Name: Enzyme Linked Immunoabsorbent Assay, *Toxoplasma Gondii*

Device Trade Name: Access® Toxo IgM II Reagents for use on the Access® Immunoassay Systems

Device Class: Class II

Applicant's Name and Address: Beckman Coulter, Inc.
Immunodiagnostics Development Center
1000 Lake Hazeltine Drive
Chaska, MN 55318

Date: August 22, 2000

2.0 Legally Marketed Device

The modified Access® Toxo IgM II Immunoassay claims substantial equivalence to the Access® Toxo IgM Immunoassay currently in commercial distribution.

FDA 510(k) Number: K973448

3.0 Device Description

The Access® Toxo IgM II reagents consist of reagent packs, controls, QC, substrate, and wash buffer.

- The Access® Toxo IgM II Reagent Packs contain specific reagents for the *in vitro* diagnostic measurement of *Toxoplasma gondii*-specific IgM antibody: Inactivated *T. gondii* Ag – *T. gondii* (P30)-specific mouse monoclonal antibody - alkaline phosphatase (bovine) conjugate in buffer, paramagnetic particles coated with sheep monoclonal anti-human IgM antibody in buffer and diluent with TRIS buffer, surfactant, and protein.

- The Access® Toxo IgM II Controls are a set of reactive and non-reactive calibration controls for use in conjunction with the Access Toxo IgM II assay to generate a cut off value. Each set contains one vial of human serum negative and one vial of human serum positive for *Toxoplasma gondii*-specific IgM antibody with preservatives.

- The Access® Toxo IgM II QC Controls set consists of reactive and non-reactive quality control materials intended for monitoring system performance of the Access Toxo IgM II assay. Each set contains three vials of human serum negative and three vials of human serum positive for *Toxoplasma gondii*-specific IgM antibody with preservatives.

- The Access® Substrate, Lumi-Phos* 530, is a dioxetane-based chemiluminescent substrate. After addition of alkaline phosphatase, the substrate is dephosphorylated resulting in the spontaneous release of light. This light is measured by a luminometer.

- The Access® Wash Buffer consists of Tris buffered saline containing surfactant and preservatives. The wash buffer is used for the following: 1) clean the pipetting probe tip in the Access Immunoassay Analyzers, 2) wash paramagnetic particles to remove unbound analyte and excess reagents in each reaction, and 3) as a diluent in designated assays.

4.0 Principles of the Procedure

The Access Toxo IgM II assay is an immunoenzymatic assay and uses the immunocapture principle. The sample to be tested is added to a reaction vessel with paramagnetic particles coated with human IgM-specific sheep polyclonal antibody as capture antibody. After incubation in the reaction vessel, separation in a magnetic field and washing remove materials not bound to the solid phase. Then a complex formed with *T. gondii* (P30)-specific monoclonal antibody that has been labeled with alkaline phosphatase is added to the reaction vessel. After a second incubation and a second washing, a chemiluminescent substrate, Lumi-Phos530, is added and light generated by the reaction is measured with a luminometer. The photon production is a function of the amount of enzyme conjugate present at the end of the reaction. The light quantity measured for a sample allows a determination of the presence of *T. gondii*-specific IgM antibody, by comparison with a cut off value defined during the assay calibration on the instrument. If the light production is equal to or greater than the cut off value, the sample is considered reactive in the Access Toxo IgM II assay.

5.0 Indications for Use

The Access® Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum, using the Access® Immunoassay Systems. The Access® Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with an anti-*Toxoplasma gondii* IgG antibody assay. Note: This assay has not been cleared/approved by the FDA for the screening of blood or plasma donors in the United States.

6.0 Description of the Modification to the Legally Marketed Device

The formulation of the Access Toxo IgM assay has been modified to improve specificity while maintaining stability. The method of calibration has been modified to clarify the use as a qualitative assay. Labeling changes have been made to

- reflect results from the completed verification studies, and
- to incorporate formulation changes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 31 2000

Ms. Jan Olsen
Staff Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K002453
Trade Name: Access® Toxo IgM II Reagents for use on the Access® Immunoassay Analyzer
Regulatory Class: II
Product Code: LGD
Dated: August 9, 2000
Received: August 10, 2000

Dear Ms. Olsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 1 C: **INDICATIONS FOR USE STATEMENT**

510(k) Number:

Device Name: Access® Toxo IgM II Reagents for use on the Access® Immunoassay Analyzer

Indications for Use:

The Access® Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum, using the Access® Immunoassay Systems. The Access® Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with an anti-*Toxoplasma gondii* IgG antibody assay. Note: This assay had not been cleared/approved by the FDA for the screening of blood or plasma donors in the United States.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Duchow

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002453

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)